EFW
AF
3761

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPELLANT:	Christer STRÖM	CONFIRMATION NO. 8832
SERIAL NO.:	09/922,504	GROUP ART UNIT: 3761
FILED:	August 3, 2001	EXAMINER: Michael G. Mendoza
TITLE:	"VENTILATOR"	

MAIL STOP APPEAL BRIEF-PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPELLANT'S MAIN BRIEF ON APPEAL

S I R:

In accordance with the provisions of 37 C.F.R. §1.192, Appellant herewith submits his Main Brief in support of the appeal of the above-referenced application.

REAL PARTY IN INTEREST:

The real party in interest is the assignee of the application, Maquet Critical Care AB, a Swedish corporation.

RELATED APPEALS AND INTERFERENCES:

There are no related appeals and no related interferences.

STATUS OF CLAIMS:

Claims 1-7 are the subject of the present appeal, and are directed to a ventilator. In an Amendment filed October 14, 2003, method claims 8-14 were added, however, in the Final Office Action dated January 12, 2004 the Examiner imposed a restriction requirement between original claims 1-7 and new method claims 8-14, and stated that since an action on the merits had already been rendered as to claims 1-7, those claims have been constructively elected, and claims 8-14 were withdrawn from consideration.

This Brief is accompanied by an Amendment canceling claims 8-14, which Appellant assumes will be entered.

STATUS OF AMENDMENTS:

As noted above, an Amendment canceling claims 8-14 has been filed simultaneously herewith and therefore at this time the status of this Amendment is not known, but Appellant assumes it will be entered.

SUMMARY OF THE INVENTION:

Mechanical ventilation is employed to control or support a patient's breathing. Breathing gas at a positive pressure is supplied to the patient. In many instances, ventilation is a vital necessity for the patient, however, the treatment in itself is not without risks. Numerous studies of animals suggest that ventilation can initiate or aggravate lung damage. A major contributory reason for this is the mechanical stress to which the pulmonary system may be subjected during ventilation. In particular, damage can develop or be aggravated when alveoli in the lungs cyclically open and collapse during inspiration and expiration. (p. 1, l. 10-16)

Moreover, some patients suffer from such severe conditions that using a treatment that can cause some damage to the lungs is the only way to save the patient's life. (p. 1, l. 17-18)

One way to prevent alveolar collapse is to impose a positive pressure on the lungs, even during expiration, with a positive end-expiratory pressure (PEEP). However, PEEP cannot be set too high, since a high PEEP can subject the lungs to harmfully high pressure during inspiration. An excessive inspiratory pressure can impede blood perfusion in the lungs (causing poorer oxygenation of the blood) and even inflicting damage to pulmonary tissue. (p. 1, l. 19-23)

Recruitment phases can be employed instead of a constantly high PEEP. During a recruitment phase, the pulmonary alveoli are opened with a pressure (usually higher than the normal inspiratory pressure for the patient), enabling them to remain open when exposed to a lower pressure during a subsequent period of treatment. The recruitment phase is repeated as needed. (p. 1, l. 24-28)

The ventilator set forth in the claims on appeal has an inspiratory unit and an expiratory valve for regulating a flow of breathing gas, and a control unit for controlling the inspiratory unit and the expiratory valve, wherein the control unit controls the inspiratory unit and the expiratory valve to generate a recruitment phase with an elevated basic pressure for the breathing gas, upon which a number of breaths is superimposed at a faster breathing rate.

FIG. 1 shows a ventilator 2 according to the invention. The ventilator 2 is connectable to a patient 4 in order to supply and evacuate breathing gases. (p. 3, l. 18-19)

Breathing gas is delivered to the ventilator 2 through a first connector 6A and a second connector 6B, and an inspiratory unit 8 mixes the gases in the right proportion and with the right pressure and flow. (p. 3, l. 20-22)

The breathing gas is then carried to the patient 4 in an inspiratory line 10 and from the patient 4 back to the ventilator 2 in an expiratory line 12. (p. 3, l. 23-24)

An expiratory valve 14 then regulates the outflow of breathing gas from the ventilator 2.

The inspiratory unit 8 and expiratory valve 14 are controlled by a control unit 16 in order to generate the pressure and flows to which the patient 4 is to be subjected. (p. 3, l. 25-27)

Supplying the patient 4 with recruitment phases is possible with the ventilator. One example of such a phase is shown in FIG. 2. The recruitment phase is shown with a curve 18 in a pressure-time (P-t) diagram. In the recruitment phase, pressure from the basic pressure (PEEP), which can range from 0 to a positive pressure of 10-15 cmH_2O (or higher if the situation calls for it), is raised to an elevated basic pressure Pr. The elevated pressure Pr can be up to 80 cmH_2O. Breaths 20 are then superimposed on this basic pressure Pr. The breaths 20 are pressure-regulated and have a pressure amplitude ΔP from 1 to 10 cmH2O. The superimposed breaths 20 are also imposed at a faster rate, i.e. from 50 to 200 breaths/minute. (p. 3, l. 28 – p. 4, l. 4)

The recruitment phase 18 has a duration tr lasting 10 to 100 seconds. (p. 4, l. 5)

The objective of the recruitment phase is to open regions of the lung containing collapsed alveoli. (p. 4, l. 6-7)

FIG. 3 shows an alternative version of the recruitment phase. It depicts a volume-time (V-t) curve 22. As in the preceding example, an elevated basic pressure is imposed. In normal instances, this would generate an effect similar to the curve 24, but the curve 22 is instead achieved because of superimposed volume-controlled breaths. These breaths have a tidal volume of 1 to 100 ml. (p. 4, l. 8-12)

As the FIG. 3 shows, the curve 22 ends with a larger total volume than the curve 24 at the end of the recruitment phase. This is because the superimposed breaths assist in opening more alveoli. (p. 4, l. 13-15)

ISSUES:

The following issues are presented in this Appeal:

Whether the subject matter of claims 1-4 and 7 is anticipated under 35 U.S.C. §102(b) by United States Patent No. 5,862,802 (Bird); and

Whether the subject matter of claims 5 and 6 would have been obvious to a person of ordinary skill in the field of ventilator design and operation under the provisions of 35 U.S.C. §103(a), based on the teachings of Bird.

GROUPING OF CLAIMS:

The patentability of claims 5 and 6 does not stand or fall together with the patentability of claims 1-4 and 7, and separate arguments for the patentability of claims 5 and 6 are set forth below.

ARGUMENT:

Recruiting a lung is a procedure that is well known to those of ordinary skill in the field of ventilator design and operation, and is for the purpose of opening pulmonary alveoli. With a ventilator, recruitment is conducted by operating the ventilator in a recruitment phase of relatively brief duration, wherein a pressure, which is usually higher than the normal inspiratory pressure for the patient, is supplied to the lung. This brief administration of higher pressure enables the alveoli to remain open during a subsequent period of treatment involving lower pressures.

The ventilator set forth in claim 1 explicitly states that it is operated in a recruitment phase. Appellant recognizes that, for the purpose of an anticipation rejection, if the Bird reference coincidentally happened to operate in a manner as described in claim 1, even if this were not explicitly recognized in the Bird reference as being for the purpose of recruitment, such operation of the bird reference nevertheless would be relevant to the patentability of claim 1. (As discussed in detail

below, Appellant does not agree that the Bird reference operates in a manner comparable to claim 1.) Nevertheless, for the obviousness rejection of claims 5 and 6, the complete absence of any discussion of recruitment or recruitment phases in the Bird reference is relevant, since a person of ordinary skill in the field of ventilator design and operation would have no basis whatsoever to consult the Bird reference for obtaining information or solutions relating to recruitment.

In the Final Rejection, the Examiner cited Figure 24 and Figure 32 of the Bird reference, and the language at column 76, lines 20-22 of the Bird reference, as allegedly teaching that the ventilator disclosed in the Bird reference could be operated in a manner comparable to the ventilator set forth in claim 1. Although the waveforms shown in those figures of the Bird reference bare a superficial resemblance to the waveforms shown in Figures 2 and 3 of the present application, they are not achieved by operating the ventilator disclosed in the Bird reference in the same manner as set forth in claim 1, and specifically they do not involve, and cannot involve, any controlled operation of the expiratory valve, as explicitly set forth in claim 1.

Claim 1 explicitly states that the recruitment phase with an elevated basic pressure for the breathing gas, with a plurality of breaths superimposed on the elevated basic pressure and an increased breathing rate with no withdrawal of the breathing gas, is achieved by controlling the inspiratory unit and the expiratory valve to regulate a flow of breathing gas.

In the Bird ventilator, separate gas lines are used to supply the "normal" breathing gas to the patient and the superimposed high frequency oscillating pulses. This is described at column 10, lines 45-54. Moreover, as explicitly stated at column

3, lines 4-8 in the Bird reference, the superimposed oscillations result from small volumes of gas being actively supplied and withdrawn. This is entirely typical and conventional for high frequency oscillation devices, of which the Bird is an example.

In the Bird reference, there is no active control of the expiration valve. In the basic embodiment shown in Figure 1, the expiration valve is the valve 228, and it can be seen from Figure 1 that there is no control line at all connected to that valve, and therefore there cannot be any controlled operation of the expiration valve 228 in the Bird reference for any purpose, much less for achieving the type of operation that is explicitly set forth in claim 1.

In other embodiments of the Bird reference, lines are shown connected to the expiratory valve in those embodiments, however, those lines are merely for the purpose of using gas exiting from the expiratory valve for feedback purposes, or for supply to a pressure or volume gauge. None of those lines are used for controlling operation of the expiratory valve.

Therefore, regardless of whether the aforementioned waveforms shown in Figures 24 and 32 of the Bird reference bare a superficial resemblance to the waveforms of Figures 2 and 3 of the present application, they are not, and cannot, be produced in the manner explicitly set forth in claim 1 on appeal. There is no control of the expiratory valve in the Bird reference, and the oscillations are superimposed on the base line breathing gas by active supply and withdrawal of small amounts of gas, which is contrary to the explicit statement in claim 1 that the breaths are superimposed without the withdrawal of breathing gas.

This makes sense when, as noted above, it is remembered that the Bird reference is not at all concerned with recruitment, but instead, in the embodiments

associated with the waveforms shown in Figures 24 and 32, is concerned with high frequency oscillation ventilation.

As can be seen from Figure 2 of the present application and the associated descriptions cited above, the breaths 20 are superimposed on the basic pressure Pr in such a way that they oscillate between the basic level Pr and the "imposed" pressure Pr+ΔP. This can be compared to Figures 6, 8 and 9 of the Bird reference, which distinctly show that the superimposed pulses oscillate around an average value, as most clearly seen in Figure 8. This high frequency oscillation ventilation is the same type of waveform that is represented in the other Figures 24 and 32 of the Bird reference.

Therefore, the Bird reference does not disclose all of the elements of claim 1 as arranged and operating in that claim, and does not anticipate claim 1, nor any of the claims 2-4 and 7 depending therefrom.

As noted above, claims 5 and 6 were rejected under 35 U.S.C. §103(a) based on the Bird reference, rather than as being anticipated by Bird. This means that the aforementioned fact that the Bird reference does not provide any teachings whatsoever with respect to recruitment is highly relevant with regard to claims 5 and 6. Although the Bird ventilator, like many other conventional ventilators, has a multitude of settings, and therefore it is not surprising that such settings may, by coincidence, be the same as or similar to the settings set forth in claims 5 and 6, there is no reason why a person of ordinary skill in the art would rely on the Bird reference to employ any of those settings in the context of a recruitment phase. Moreover, at least claim 5 states that the increased breathing rate is set as a percentage of the predetermined normal breathing rate by the control unit controlling

the inspiratory unit in the expiratory valve. As noted above, the Bird reference provides no teaching to control the expiratory valve for any purpose, and therefore even if the Bird reference happens to have some other type of control arrangement for setting an increased breathing rate, it does not involve control of the expiratory valve. Claim 6 depends from 5 and therefore the setting by the control unit set forth in claim 6 must be in the same manner as set forth in claim 5, and therefore the same arguments apply with regard to claim 6.

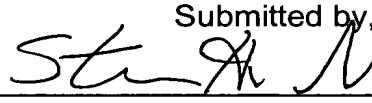
Claims 5 and 6, therefore, would not have been obvious to a person of ordinary skill in the field of ventilator design and operation based on the teachings of the Bird reference.

CONCLUSION:

For the foregoing reasons, Appellant respectfully submits the Examiner is in error in fact and in law in rejecting the claims on appeal. Reversal of these rejections is proper, and the same is respectfully requested.

This Appeal Brief is accompanied by a check for the requisite fee in the amount of $330.00.

Submitted by,



(Reg. 28,982)

SCHIFF, HARDIN LLP
CUSTOMER NO. 26574
Patent Department
6600 Sears Tower
233 South Wacker Drive
Chicago, Illinois 60606
Telephone: 312/258-5790
Attorneys for Appellant(s).

CERTIFICATE OF MAILING

I hereby certify that an original and two copies of this correspondence are being deposited with the United States Postal Service as First Class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on June 9, 2004.

Steven H. Noll

STEVEN H. NOLL

APPENDIX "A"

1. A ventilator comprising:

an inspiratory unit;

an expiratory valve;

a control unit for controlling said inspiratory unit and said expiratory valve to regulate a flow of breathing gas by generating a recruitment phase with an elevated basic pressure for said breathing gas, with a plurality of breaths superimposed on said elevated basic pressure and an increased breathing rate with no withdrawal of said breathing gas.

2. A ventilator as claimed in claim 1 wherein said control unit controls said inspiratory unit and said expiratory valve to produce said elevated basic pressure in a range from 10 to 80 cmH_2O.

3. A ventilator as claimed in claim 1 wherein said control unit controls said inspiratory unit and said expiratory valve to generate said superimposed breaths at a pressure in a range from 1 to 10 cmH_2O.

4. A ventilator as claimed in claim 1 wherein said control unit controls said inspiratory unit and said expiratory valve to generate said increased breathing rate in a range from 50 to 200 breaths/minute.

5. A ventilator as claimed in claim 1 wherein said control unit controls said inspiratory unit and said expiratory valve to set said increased breathing rate as a percentage of a predetermined normal breathing rate.

6. A ventilator as claimed in claim 5 wherein said control unit sets said percentage to a percentage in a range between 110 % and 1000%.

7. A ventilator as claimed in claim 1 wherein said control unit controls said inspiratory unit and said expiratory valve to generate said recruitment phase for a duration in a range between 100 to 100 seconds.